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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Galdes et al.

Serial No: 09/435,733

Filed: November 8, 1999

For: Methods and Compositions for  
Treating or Preventing Peripheral  
Neuropathies

Attorney Docket No. CIBT-P02-052

Art Unit: 1646

Examiner: M. Brannock

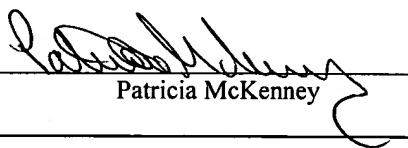
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Assistant Commissioner of Patents  
Washington, D.C. 20231

**AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Restriction Requirement, which was mailed from the U.S. Patent and Trademark Office on April 26, 2001, in the above-identified patent application, Applicants elect with traverse Group I, drawn to methods of treatment or prevention using a Sonic hedgehog polypeptide. Applicants elect this invention with traverse, because the claims in Group I encompass subject matter of claims grouped by the Examiner in Groups II, III, IV, V, VI, and VII and could thus be examined simultaneously without any additional burden.

In particular, Applicants respectfully point out that the claims of Group I are not limited to uses of Sonic hedgehog polypeptide, but also include within their scope related family members that share functional homology with Sonic hedgehog, namely Desert hedgehog, Indian

hedgehog, and Tiggie-winkle hedgehog, as described in dependent claim 12. Applicants respectfully request that claims 1-23, 30-31, 41, and 44-51 be examined together.

Additionally, Applicants point out that the claims of Group I are drawn "to methods of treatment and or prevention using hedgehog polypeptides," and include within their scope methods for treatment using gene therapy as described in independent claim 43. Since the examination of methods of treatment using hedgehog polypeptides will certainly include within its scope searches regarding the use of gene therapy as a method of treatment, the examination of such claims simultaneously will not increase the scope of the Examiner's search. Applicants respectfully request that claims 1-23, 30-31, 41, and 43-51 be examined together.

Finally, Applicants note that the claims of Group I also include within their scope the claims of Group V and VI. Specifically, claims 1-6 and 30, of Group I, are directed at the use of hedgehog or patched therapeutics, including such therapeutics that affect signaling through the hedgehog/patched pathway. Searches relating to the use of either organic small molecules or antisense nucleic acids, dependent claims 24-29 and 32-40, and independent claim 42, would be within the scope of searches relating to the claims of Group I, and thus examining such claims together does not represent an undue burden on the Examiner.

For the reasons outlined above, Applicants respectfully request that claims 1-51 be examined together. The Examiner is additionally reminded that in accordance with MPEP 809, "...linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn."

The Examiner further requested that we elect a distinct species of treatment that would be defined by a single patient population. Applicants respectfully traverse this restriction, but select for search purposes only diabetic neuropathy. Applicants assert that the maladies listed in the claims offer a subset of illness with which neuropathy is associated. The claims are already directed at a single patient population, those suffering from a form of neuropathy. The Examiner is reminded that in accordance with MPEP 809.02(c), the neuropathies listed in claim 47 are a subset of the broader claims related to the general condition of neuropathy. As such, if the elected species is allowed than the linking species must also be allowed.

Please enter the following amendments

In the claims: